1 SCOPE
This SOP applies to administrative processes of making and the approval of minutes for all regular and special IBC meetings.

2 PURPOSE
2.1 This SOP establishes the process to take minutes of all meetings of the IBC.
2.2 This process begins when the meeting is called to order.
2.3 This process ends when a set of meeting minutes are finalized and approved by the IBC.

3 RESPONSIBILITIES
3.1 IBC members (primary and alternate) carry out this procedure.

4 PROCEDURE
4.1. Use the minutes template to record minutes.
4.2. Record at the beginning of the minutes:
4.2.1. “Members Present”: Record the following information on IBC members present at any time during the meeting and having voting status at least once during the meeting:
   4.2.1.1. Name;
   4.2.1.2. Status;
   4.2.1.3. Whether the IBC member is an alternate; and
   4.2.1.4. Whether the IBC member attended by teleconference.
4.2.2. “Others Present”: Record the following information on individuals present at any time during the meeting who never have voting status:
   4.2.2.1. Name.
   4.2.2.2. Role
4.3. State the total number of regular members on the current IBC roster and the number of members required for quorum.
4.4. If IBC members are present by teleconference, indicate whether they received all pertinent material before the meeting and were able to actively and equally participate in all discussions.
4.5. Record the time the meeting is called to order.
4.6. Record a summary of the discussion of items unrelated to the review of specific research.
4.7. For each item related to specific research:
4.7.1. Record the type of review.
4.7.2. Record relevant information about the research:
   - Title
   - Principal investigator
   - IBC number
   - Documents reviewed
4.7.3. When needed for clarity, summarize previous IBC actions.
4.7.4. If any item is not acted upon, record the reason.
4.7.5. If a consultant provided an oral report, summarize the key information provided.
4.7.6. If there were no controverted issues, record it. If there were any controverted issues (IBC members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any.

4.7.7. Record each motion.
   4.7.7.1. For a motion of “Approve” or “Conditionally Approve” related to an initial or continuing review submission, record the approval period and the findings supporting these determinations.
   4.7.7.2. For a motion of “Conditionally Approve,” record the IBC’s modifications required to secure approval and the reasons for those modifications.
   4.7.7.3. For a motion of “Defer” record the IBC’s reasons and recommendations.
   4.7.7.4. For a motion of “Disapprove,” record the IBC’s reasons.
   4.7.7.5. For a motion of “Tabled,” record the specific activities suspended and the IBC’s recommendations, if any.

4.7.8. Record the vote as the numbers:
   - “For”: Voting for the motion.
   - “Against”: Voting against the motion
   - “Abstain”: Present for the vote, but not voting “For” or “Against”
   - “Absent”: Not present for reasons other than a conflict of interest
   - Record the names of absent members (members in attendance at the meeting, but sent absent from the room for the vote)
   - “Recused”: Not present for discussion and voting due to a conflict of interest
   - Record the names of recused members
   - Non-Voting Status: Present at the meeting but not in voting status (in voting status for some items but not in voting status for all items)
   - Record the names of members present in non-voting status

4.8. Record the time the meeting is adjourned.

4.9. Provide the draft copy of the minutes to the Meeting Chair and IO for review. Forward the final copy to convened IBC members for review.

4.10. Include approval of minutes as an agenda item in the following IBC meeting and vote for the approval of minutes.

5 REFERENCED MATERIALS
   5.1. Federal Regulation 21 CFR §56.115(a)(2)
   5.2. Federal Regulation 45 CFR §46.115(a)(2)

6 VERSION HISTORY
   6.1 Version 1.0.